



DEPARTMENT OF HEALTH & HUMAN SERVICES

MAY 6 2008

Food and Drug Administration  
Rockville MD 20857

Re: Omnaris  
Docket No.: 2007E-0131

The Honorable Jon Dudas  
Undersecretary of Commerce for Intellectual Property  
Director of the United States Patent and Trademark Office  
Mail Stop Hatch-Waxman PTE  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 5,482,934, filed by Altana Pharma AG, under 35 U.S.C. section 156 *et seq.* We have reviewed the dates contained in the application and have determined the regulatory review period for Omnaris (ciclesonide), the human drug product claimed by the patent.

The total length of the regulatory review period for Omnaris (ciclesonide) is 3,196 days. Of this time, 2,893 days occurred during the testing phase and 303 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: January 21, 1998.

FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 21, 1998.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: December 22, 2005.

FDA has verified the applicant's claim that the new drug application (NDA) for Omnaris (ciclesonide) (NDA 22-004) was initially submitted on December 22, 2005.

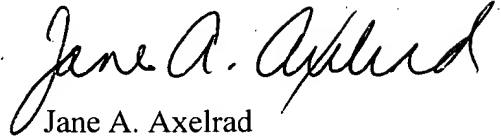
3. The date the application was approved: October 20, 2006.

FDA has verified the applicant's claim that NDA 22-004 was approved on October 20, 2006.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

A handwritten signature in black ink, reading "Jane A. Axelrad". The signature is fluid and cursive, with the first name "Jane" and last name "Axelrad" clearly legible.

Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

cc: Gary M. Nath  
Nath and Associates  
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